AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

JANSSEN RESEARCH & DEVELOPMENT LLC
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES

Amendment No. 0003
Effective Date of Amendment: Upon Last Signature in Section III

Other Transaction Agreement No. HHSO100201700018C
Effective Date of Agreement: August 15, 2017

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

[*Remainder of this Page Intentionally Left Blank; See Next Page for Description*]

I. AMENDMENT PURPOSE

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0003 bilaterally (i) (b) (4) [redacted], (ii) (b) (4) [redacted] (iii) update the Recipient's Key Personnel and the Government's personnel working under the Agreement, and (iv) make administrative changes..

II. AMENDMENTS TO AGREEMENT

A. Exercise Option Period No. 1

1) Pursuant to Agreement Article II(A), Option Period No. 1 is hereby exercised, thereby extending the Agreement's expiry by one (1) year from December 31, 2018 to December 31, 2019.

2) Exhibit A Joint Oversight Committee – Decision Document (June 28, 2018), which evidences the agreement with the updated Option 1 budget, is incorporated and attached to this Amendment No. 0003.

3) For clarity, the Agreement's *potential* Period of Performance, including every Option, that is set forth on the Agreement's Signature Page remains unchanged at "August 15, 2017–August 14, 2022."

B. (b) (4) Under This Agreement

1) Pursuant to Agreement Amendment No. 0002 Section II(G)(2), (b) (4) [redacted].

2) (b) (4) [redacted]

C. (b) (4) [redacted]

1) (b) (4) [redacted]

2) (b) (4) [redacted]

(b) (4)

D. (b) (4)

(b) (4)

(b) (4)

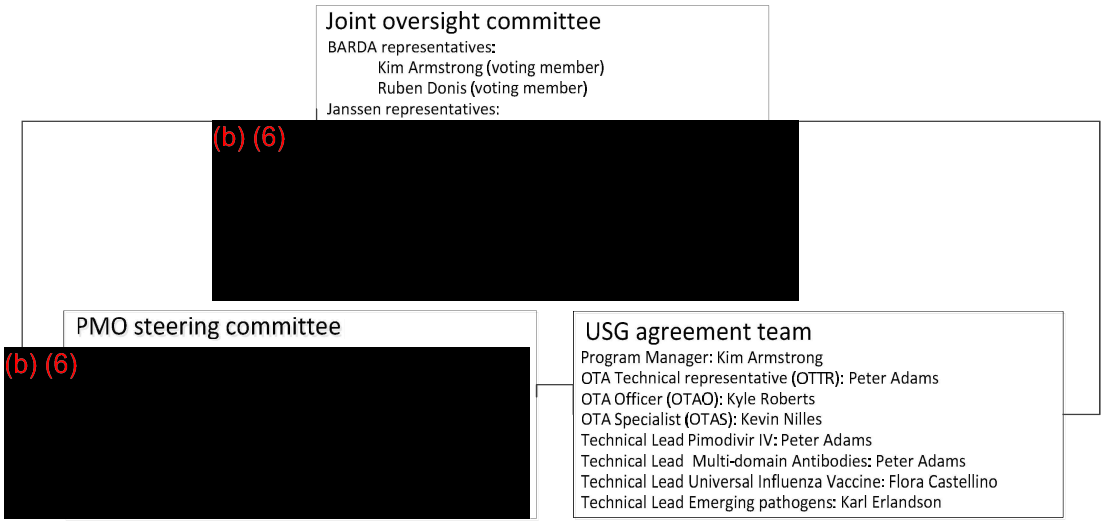
F. Government's Option Period No. 1 Accounting and Appropriation Data

Obligation Amount:	$41,327,515.00
Requisition No.:	OS233801
Object Class:	25103
Appropriation:	75X0140
CAN:	199TWSB: (b) (4)
CAN:	199TWRY: (b) (4)
FY Availability of Appropriation for Obligation:	
FY Funds Are Obligated:	FY2019

G. Total funds obligated to this Agreement by the Government increase by $41,327,515 from $43,588,145 to $84,915,660. (b) (4) (b) (4)

H. Update on Recipient's Key Personnel and the Government's personnel working under the Agreement

1. Article IV *Management of the Project* Section A(3) *Organizational chart* is changed by deleting the chart and replacing it with the following:



2. Article V *Agreement Administration* is changed by

a. revising the Paragraph entitled "Government Points of Contact" as follows:

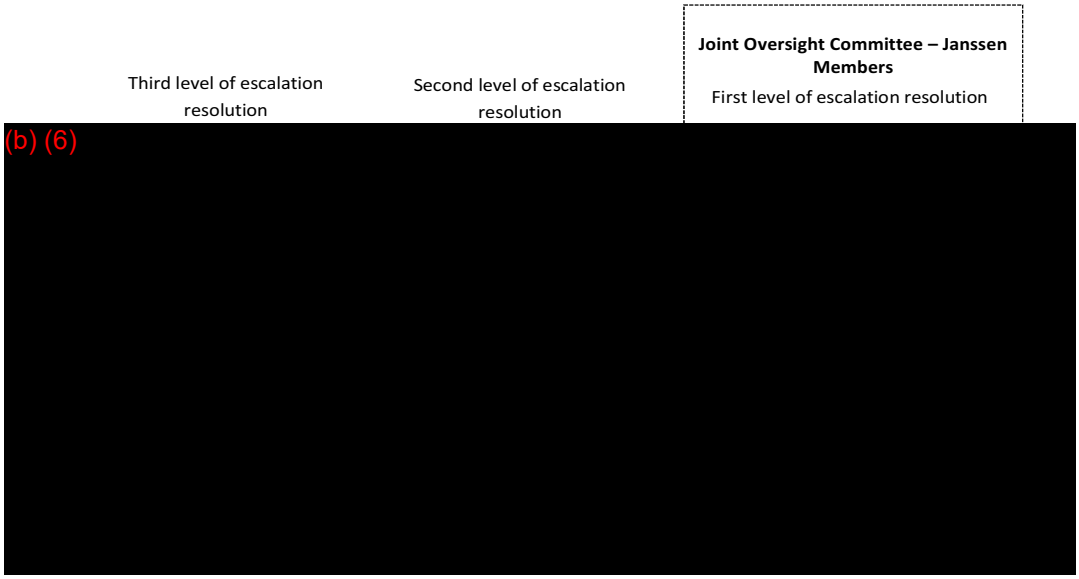
Other Transaction Agreement Technical Representative (OTTR) is

(NAME) (b) (6)
(TITLE) (b) (6) (b) (6)
(EMAIL) (b) (6)

b. adding the following as the Recipient's Co-Principal Investigator (Co-PI):

(NAME) (b) (6)
(TITLE) (b) (6)
(EMAIL) (b) (6)

3. Attachment 3 *Janssen Escalation Procedure Diagram* is changed by deleting the diagram and replacing it with the following:



Notes: (1) This chart reflects an example of the escalation points of contract within the Consortium for purposes of resolving a dispute with the Government.
(2) Consortium Voting members of the Joint Oversight Committee (JOC)
(3) Consortium Non-voting members of JOC

I. The following administrative updates to the existing agreement have been made in this Amendment No. 0003:

1. ARTICLE I: SCOPE OF THE AGREEMENT, SECTION B Definitions - The following definition shall be updated:
Recipient: Janssen Research & Development, LLC ("JRD" or "Janssen") acting on its own behalf and on behalf of the Consortium and each Consortium Member.

2. Attachment 2: REPORT REQUIREMENTS (attached hereto as Exhibit D), is updated to:

   a. Correct the Item Description Numbering beginning at item 16, Final Report is renumbered 17 and subsequent report numbers are corrected accordingly

   b. Clarified the different Delivery date between the Monthly Technical report and the Business status report.

   c. Correction to Deliverables Table to adjust typos carried forward from previous contract reference

III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC		U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY
(b) (6) [redacted]		(b) (6) [redacted]
DATE: 27 DEC 2018		DATE: 27DEC2018

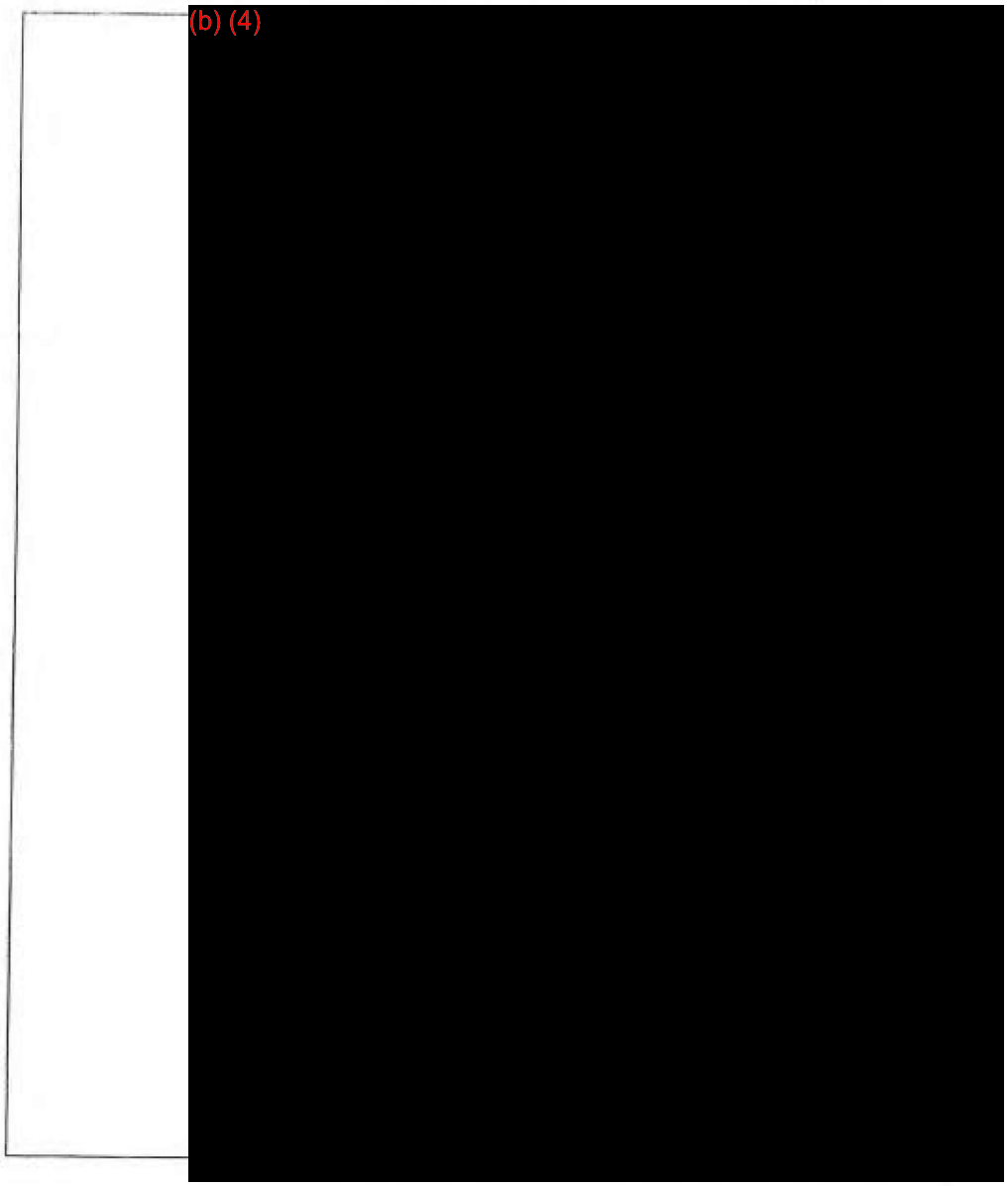
EXHIBIT A

Joint Oversight Committee – Decision Document

Dated June 28, 2018

BARDA/Janssen Research & Development LLC - Influenza and Emerging Pathogens OTA
Contract Number: HHSO100201700018C
Joint Oversight Committee – Decision Document

Date:	28 June 2018	
JOC Meeting Number:	3 (off-line)	
JOC Participants:	(b) (6)	BARDA reps: - Melissa Willis (voting) - Ruben Donis (voting)
Invited participants:	Janssen reps: NAP (off-line)	BARDA reps NAP (off-line)
Assets Reviewed:	(b) (4)	
Decision Requested, Rationale and Budget Impact:		


(b) (4)

JOC Member Approvals:

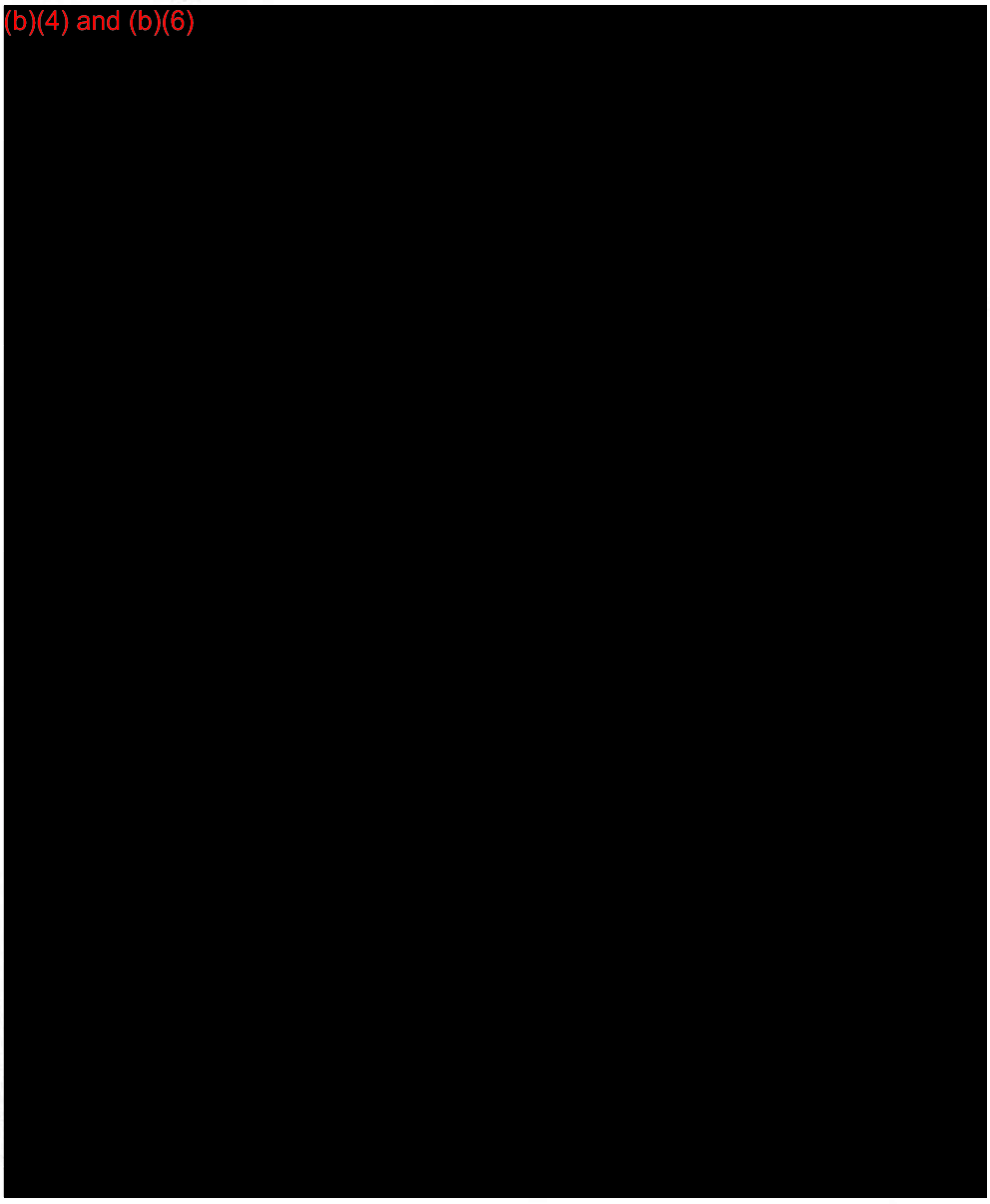


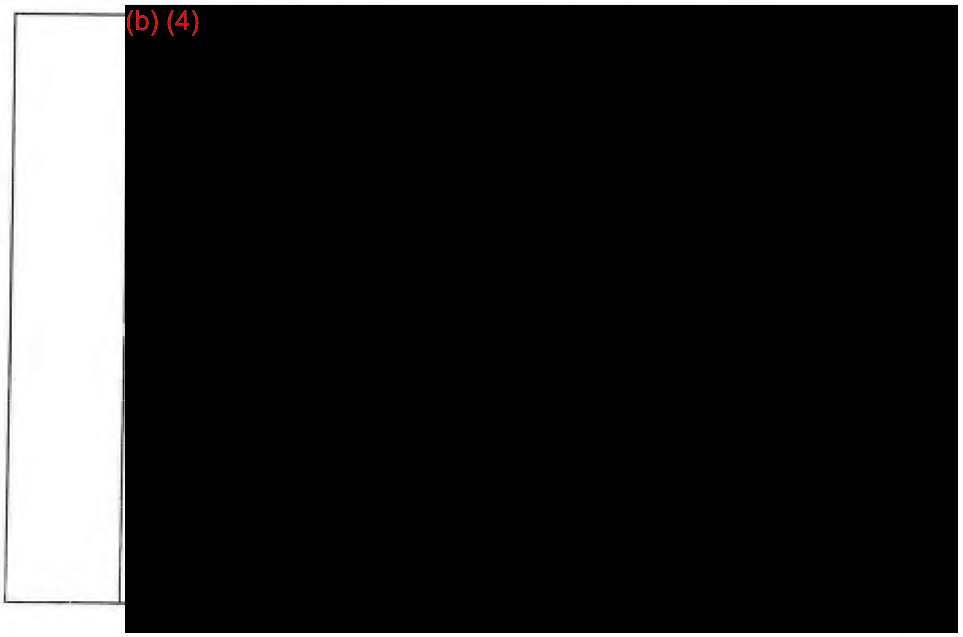
EXHIBIT B

Joint Oversight Committee – Decision Document

Dated August 9, 2018

BARDA/Janssen Research & Development LLC - Influenza and Emerging Pathogens OTA
Contract Number: HHSO100201700018C
Joint Oversight Committee – Decision Document

Date:	9 August 2018	
JOC Meeting Number:	4 (off-line)	
JOC Participants:	(b) (6)	BARDA reps: - Kimberly Armstrong (voting) - Rubes Donis (voting)
Invited participants:	Janssen reps: NAP (off-line)	BARDA reps NAP (off-line)
Assets Reviewed:	(b) (4)	
Decision Requested, Rationale and Budget Impact:		



JOC Member Approvals:

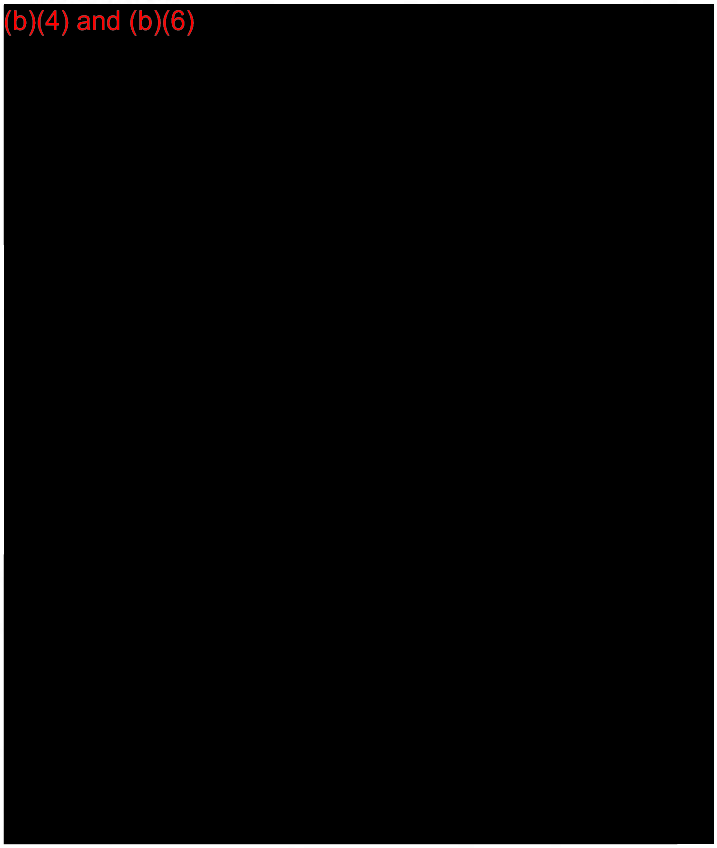


EXHIBIT C

(b) (4)

(b) (4)

WP 5.2 Clinical Studies

(b) (4)

WP 5.3 CMC

(b) (4)

WP 5.4 Regulatory

(b) (4)

PROJECT MANAGEMENT

Asset Project Management (one WP per asset)

These WPs include the Program Management activities associated with each of the assets. Each asset will have an Asset Project Management Leader (Asset PML) who will oversee their specific Project Management requirements. This includes conducting frequent and regular Project Management Team (PMT) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The PMT of each asset will also include relevant functional Project Managers and a Finance Representative. Each asset will also have an Asset Technical Lead who will oversee their specific Technical requirements. This includes conducting frequent and regular Compound Development Team (CDT) meetings to define the overall development strategy. The CDT of each asset will include Technical Lead, Preclinical Leader, Clinical Leader, the CMC Leader and the Regulatory Leader. Additional expertise required for executing asset-specific work possibly including subcontractors may be added as part of the PMT & CDT.

WP 5.6 Joint Oversight Committee

The Joint Oversight Committee (JOC) is the larger decision making body that provides guidance, direction and control to the projects to ensure execution of the projects according to the SOW. The JOC will discuss and approve any changes to the SOW. To that extent, the JOC will meet at critical decision points in the program, but no less than two times per year, preferably face to face or alternatively by WebEx or telephone conference. Ad hoc meetings will be organized when urgent matters arise. The JOC will consist of voting and non-voting members from BARDA and Janssen.

Additional, non-voting members can be assigned or invited on an ad hoc basis. Decisions to reprioritize specific projects and resources as the need arises will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Janssen senior management member identified at the start of the project.

WP 5.6 PMO Steering Committee

The PMO (Program Management Organization) steering committee has dual responsibilities. One area of responsibility is the communication and coordination with BARDA regarding day to day management and execution of the project e.g. organizing meetings on a regular agreed basis. In addition, the PMO Steering Committee will coordinate all SOW activities and provide the technical and administrative infrastructure to ensure efficient planning, initiation, implementation, direction, management and completion of all tasks, including the establishment of the Compound Development Teams (CDT). These SOW activities will be coordinated by the Project Management Leader (PML). The Steering Committee will assess progress and where needed will work out strategic changes to be decided upon by the JOC. The Steering Committee consists of a group of dedicated and specialized Project Management experts, key personnel and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset area.

EXHIBIT D

REPORT REQUIREMENTS

Item Description	Delivery Date	Deliver To
1. Monthly Technical Progress Report describing project progress over the previous month.	The 15th of each month	OTAO/OTAS and OTTR via e-mail. Additionally, email invoices to PSC_Invoices@psc.hhs.gov
2. Quarterly Invoices and Business status update	Invoice: within 60 calendar days of the end of each quarter Business status update: within 15 calendar days of the invoice	
3. Bi-Weekly Conference Call Minutes	Proposed agenda 2 business days prior to call. Minutes within 7 business days following each conference call	
4. Quarterly PMO Steering Committee / Site Visit Minutes	Within 10 business days following each PMO Steering Committee /site visit	
5. Bi-annually Joint Oversight Committee minutes	Within 10 business days following each Joint Oversight Committee	
6. Portfolio Progress Milestone Presentation. Annual or event driven review of program	No later than 10 business days before Milestone Review at Joint Oversight Committee	
7. Study Protocols for each relevant non-clinical study and clinical trials	No later than 10 business days before submission to the FDA	OTAO/OTAS and OTTR via e-mail and, if requested, CD-ROM
8. Study Reports for each relevant non-clinical study and clinical trials	No later than 15 business days before submission to the FDA	
9. Manufacturing Campaign Reports for contract funded clinical trial material and registration lots	No later than 15 business days before submission to the FDA	

10. Technical Documents from contract funded activities such as Process Development Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis	Within 10 business days upon request by CO/COR or 15 business days prior to submission to FDA	
11. QA Audit Reports including findings, results and next steps. BARDA reserves the right to participate in the audits.	Within 5 business days of report completion	
12. Formal FDA Submissions of any kind pertaining to the scope of the project as necessary during Contract performance	No later than 10 business days before submission to the FDA BARDA will coordinate with Contractor for reviewing NDA sections	
13. Memo with Date and Time of Scheduled Meetings with FDA. BARDA reserves the right to attend FDA meetings relevant to contract funded activities	As soon as possible after scheduling	
14. Communications from FDA related to contract funded activities	Within 2 business days of receipt from FDA	
15. Minutes for Formal Meetings with FDA	Within 2 business days of receipt from FDA	
16. Draft Final Report	No later than 45 business days prior to contract expiration	OTAO/OTAS and OTTR via e-mail.
17. Final Report	No later than 45 Business Days prior to contract expiration	
18. Incident Report for any critical programmatic concerns, risks or potential risks	Within 96 hours of incident	OTAO/OTAS and OTTR via e-mail or telephone
19. Raw Data and Analysis Pertaining to Scope of the Project Generated Using USG Funds	Within a reasonable time after request within industry standards	OTAO/OTAS via e-mail
20. Weekly Clinical Report during Active Enrollment Periods	The Monday following the week being reported	OTTR via email

21. Clinical Site Enrollment Reporting and Updates to support the BARDA Clinical Trial Database	Submitted monthly as part of technical report	
22. Quality Agreements with Subcontractors	Within 10 business days upon request by OTAO/OTTR	OTAO/OTAS and OTTR via e-mail
22. Publications/Presentations	No later than 30 calendar days before submission for publications and 15 calendar days for presentations	OTAO/OTAS and OTTR via email

A. Monthly Technical Progress Report

On or before ninety (90) calendar days after the effective date of the Agreement and monthly thereafter throughout the term of the Agreement, Recipient shall submit or otherwise provide a monthly technical progress report. Two (2) copies shall be submitted or otherwise provided to the HHS Program Manager (or OTTR), one (1) copy shall be submitted or otherwise provided to the ASPR OTAO.

The report will detail technical progress to date and report on all problems, technical issues, major developments, and the status of external collaborations during the reporting period.

B. **Business Status Report**

The Business Status Report will be provided on a quarterly basis consistent with the invoice cycle, within fifteen (15) calendar days after invoice submission. The business status report shall provide summarized details of the resource status of this Agreement, including the status of Recipient contributions. This report will include a quarterly accounting of current expenditures as outlined in the Annual Program Plan. Any major deviations, over plus or minus 10%, shall be explained along with discussions of the adjustment actions proposed. The report will also include an accounting of any interest earned on Government funds. Recipient is reminded that interest in amounts greater than $250 per year is not expected to accrue under this Agreement. In the event that this interest does accrue on Government funds, Recipient is required to provide an explanation for the accrual in the business report. Depending on the circumstances, the Payable Milestones may require adjustment